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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,927	09/14/2000	William J. Dower	019282-000110US	1158

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 08/16/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary <i>File Copy</i>	Application No. 09/661,927	Applicant(s) DOWER ET AL.	
	Examiner Jon D Epperson	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>11</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

SUBSTITUTE RESTRICTION/ELECTION

1. Please note: There is a change in Examiner handling prosecution in the current case from Examiner Steven C. Tizio to Jon D. Epperson.

2. The Response to the Restriction Requirement submitted by applicant dated May 17, 2002, is acknowledged. Claims 25, 26, 43, 53 and 55 were amended and no claims were added or cancelled.

3. Applicant's election, with traverse, of Group I (claims 1-68) is acknowledged in Paper No. 7. Applicant's election of species is also acknowledged in Paper No. 7. The traversal will be addressed in the first action on the merits.

4. Claims 69-137 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No. 7.

5. Therefore, claims 1-68 are examined on the merits in this action. However, upon further review of the instant case, additional restrictions were deemed necessary and appropriate as specified below. Furthermore, the previous species election (see paper number 7, "Response to

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Species Election Requirement”) has been withdrawn. A new species election is required for the groups listed below.

6. Please note: After a telephonic interview with Scott Ausenhus on August 14, 2002, the restriction requirement dated July 17, 2002 (Paper no. 9) has been withdrawn and is now replaced with this substitute restriction/election (Paper no. 10) as described below.

Election/Restriction

7. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 (in part), 2-68 drawn to a method for “screening a carrier-type transport protein.” The invention is classified variously, for example, in class 436, subclass 501; class 435, subclass 7.1; class 435, DIG 2+ (depending on the type of ligand).
- II. Claims 1 (in part), 2-68 drawn to a method for “screening a ligand.” The invention is classified variously, for example, in class 436, subclass 501; class 435, subclass 7.1; class 435, DIG 2+ (depending on the type of ligand).
- II. Claims 1 (in part), 2-68 drawn to a method for “screening a carrier-type transport protein and a ligand.” The invention is classified variously, for example, in class 436, subclass 501; class 435, subclass 7.1; class 435, DIG 2+ (depending on the type of ligand).

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8. The inventions are distinct, each from the other because of the following reasons:

9. Groups I-III represent patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results (they will screen different classes of molecules). In the instant case, each Group i.e., Groups I-III, will require different reagents and, as a result, will also require different method steps. For example, Group I requires a "carrier-type transport protein", Groups II requires a "ligand" and Group III requires both a "carrier-type transport protein" and a "ligand." As a result, Groups I-III will require different method steps i.e., Group I will require method steps for the production and use of "carrier-type transport proteins", Group II will require method steps for the production and use of "ligands" and Group III will require production and use of both "carrier-type transport proteins" and "ligands" simultaneously. Furthermore, the method steps of Group III will produce different results than the method steps of Groups I and II in situations where the materials of Group III (both "carrier-type transport proteins" and "ligands") are required. Likewise, the method steps of Group II will produce different results than the method steps of Group I in situations where the materials of Group II (i.e., ligands) are required. Consequently, examining Groups I-III together will require searching different reagents, different method steps, and/or different resulting products, which in most cases will fall under many different US classification numbers. Therefore, searching Groups I-III together would represent an undue search burden. In addition, art anticipating or rendering obvious each Group i.e., Groups I-III would not render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics (e.g., a demonstrated ability to screen for a

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ligand would not render obvious an ability to screen for a carrier-type transport protein).

Consequently, Groups I-III have different issues regarding patentability and enablement and represent patentably distinct subject matter.

10. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

11. This application contains claims directed to the following patentably distinct species of the claimed inventions as set forth below.

12. If applicant elects the invention of Group I applicant is required to elect from the following patentably distinct species. Claims 1 is generic.

Subgroup 1: Species of carrier-type transport protein (see claim 1)

For the purposes of search, applicant is required to elect a single species of “carrier-type transport protein” in claim 1. Furthermore, applicant must disclose which claims read on the elected “carrier-type transport protein.” Applicant must not group all elected species together (i.e., Subgroups 1-13) and then disclose which claims read on the sum total of the elected species. Applicant must disclose which claims read ONLY on the elected “carrier-type transport protein” (i.e., what groups read ONLY on Subgroup 1).

Subgroup 2: Species of complex (see claim 1)

For the purposes of search, applicant is required to elect a single species of “complex” in step “1a” of claim 1 wherein a single specific “compound”, “reporter” and “linker” (if any) are disclosed. Furthermore, applicant must disclose which claims read on the elected “complex.” Applicant must not group all elected species together (i.e., Subgroups 1-13) and then disclose which claims read on the sum total of the elected species. Applicant must disclose which claims read ONLY on the elected “reporter” (i.e., what groups read ONLY on Subgroup 1).

Subgroup 3: Species of cells (see claim 1)

A specific single species of cells must be elected for the purposes of a search. Furthermore, applicant must disclose which claims read on the elected “species of cells.” Applicant must not group all elected species together (i.e., Subgroups 1-13) and then disclose which claims read on the sum total of the elected species. Applicant must disclose which claims read ONLY on the elected “cells” (i.e., what groups read ONLY on Subgroup 3).

Subgroup 4: Species of detecting a signal (see claim 1)

A specific single species of method for “detecting a signal” must be elected for the purposes of a search. Furthermore, applicant must disclose which claims read on the elected method for “detecting a signal.” Applicant must not group all elected species together (i.e., Subgroups 1-13) and then disclose which claims read on the sum total of the elected species. Applicant must disclose which claims read ONLY on the elected method for “detecting a signal” (i.e., what groups read ONLY on Subgroup 4).

13. If applicant elects the invention of Group II applicant is required to elect from the following patentably distinct species. Claims 1 is generic.

Subgroup 5: Species of ligand (see claim 1)

For the purposes of search, applicant is required to elect a single species of “ligand” in claim 1. Furthermore, applicant must disclose which claims read on the elected “ligand.” Applicant must not group all elected species together (i.e., Subgroups 1-13) and then disclose which claims read on the sum total of the elected species. Applicant must disclose which claims read ONLY on the elected “ligand” (i.e., what groups read ONLY on Subgroup 5).

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Subgroup 6: Species of complex (see claim 1)

For the purposes of search, applicant is required to elect a single species of “complex” in step “1a” of claim 1 wherein a single specific “compound”, “reporter” and “linker” (if any) are disclosed. Furthermore, applicant must disclose which claims read on the elected “complex.” Applicant must not group all elected species together (i.e., Subgroups 1-13) and then disclose which claims read on the sum total of the elected species. Applicant must disclose which claims read ONLY on the elected “reporter” (i.e., what groups read ONLY on Subgroup 6).

Subgroup 7: Species of cells (see claim 1)

A specific single species of cells must be elected for the purposes of a search. Furthermore, applicant must disclose which claims read on the elected “species of cells.” Applicant must not group all elected species together (i.e., Subgroups 1-13) and then disclose which claims read on the sum total of the elected species. Applicant must disclose which claims read ONLY on the elected “cells” (i.e., what groups read ONLY on Subgroup 7).

Subgroup 8: Species of detecting a signal (see claim 1)

A specific single species of method for “detecting a signal” must be elected for the purposes of a search. Furthermore, applicant must disclose which claims read on the elected method for “detecting a signal.” Applicant must not group all elected species together (i.e., Subgroups 1-13) and then disclose which claims read on the sum total of the elected species. Applicant must disclose which claims read ONLY on the elected method for “detecting a signal” (i.e., what groups read ONLY on Subgroup 8).

14. If applicant elects the invention of Group III applicant is required to elect from the following patentably distinct species. Claims 1 is generic.

Subgroup 9: Species of ligand (see claim 1)

For the purposes of search, applicant is required to elect a single species of “ligand” in claim 1. Furthermore, applicant must disclose which claims read on the elected “ligand.” Applicant must not group all elected species together (i.e., Subgroups 1-13) and then disclose which claims read on the sum total of the elected species. Applicant must disclose which claims read ONLY on the elected “ligand” (i.e., what groups read ONLY on Subgroup 9).

Subgroup 10: Species of carrier-type transport protein (see claim 1)

For the purposes of search, applicant is required to elect a single species of “carrier-type transport protein” in claim 1. Furthermore, applicant must disclose which claims read on the elected “carrier-type transport protein.” Applicant must not group all elected species together (i.e., Subgroups 1-13) and then disclose which claims read on the sum total of the elected species. Applicant must disclose which claims read ONLY on the elected “carrier-type transport protein” (i.e., what groups read ONLY on Subgroup 10).

Subgroup 11: Species of complex (see claim 1)

For the purposes of search, applicant is required to elect a single species of “complex” in step “1a” of claim 1 wherein a single specific “compound”, “reporter” and “linker” (if any) are disclosed. Furthermore, applicant must disclose which claims read on the elected “complex.” Applicant must not group all elected species together (i.e., Subgroups 1-13) and then disclose which claims read on the sum total of the elected species. Applicant must disclose which claims read ONLY on the elected “reporter” (i.e., what groups read ONLY on Subgroup 11).

Subgroup 12: Species of cells (see claim 1)

A specific single species of cells must be elected for the purposes of a search. Furthermore, applicant must disclose which claims read on the elected “species of cells.” Applicant must not group all elected species together (i.e., Subgroups 1-13) and then disclose which claims read on the sum total of the elected species. Applicant must disclose which claims read ONLY on the elected “cells” (i.e., what groups read ONLY on Subgroup 12).

Subgroup 13: Species of detecting a signal (see claim 1)

A specific single species of method for “detecting a signal” must be elected for the purposes of a search. Furthermore, applicant must disclose which claims read on the elected method for “detecting a signal.” Applicant must not group all elected species together (i.e., Subgroups 1-13) and then disclose which claims read on the sum total of the elected species. Applicant must disclose which claims read ONLY on the elected method for “detecting a signal” (i.e., what groups read ONLY on Subgroup 13).

15. All of the above identified species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the

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starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an additional undue search burden, and election for examination purposes as indicated is proper.

- 16. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

17. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

18. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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19. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

20. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

21. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

22. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

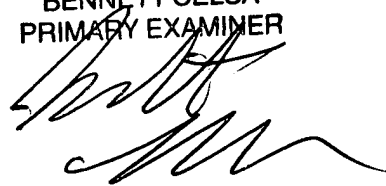
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23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D. Epperson, Ph.D. whose telephone number is (703) 308-2423. The examiner can normally be reached on Monday-Friday from 8:30 a.m. to 4:30 p.m..

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jon D. Epperson, Ph.D.
8/14/2002

BENNETT CELSA
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Bennett Celsa', is written over the printed name and title.